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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,220	11/27/2000	Wolfgang Fleischer	228.1006	8087

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New York, NY 10036

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/23/2001

Remailed 3-4-02

Please find below and/or attached an Office communication concerning this application or proceeding.

** Restarted time due to mail was
initiated & return to our office.
Restarted 3-4-02. Requested
a change of address as well.
P. Gray 3-1-02*

Office Action Summary

Application No.
09/701,220

Applicant
Fleischer

Examiner
Gollamudi S. Kishore, Ph.D

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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DETAILED ACTION

The preliminary amendment filed on 11-27-00 is acknowledged.

Since some of the claim numbers are missing, the pending claims have been renumbered according to rule 126 (missing claim numbers : 26, 31, 33, 38, 45). Claims included in the prosecution are 1-48.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes containing povidone iodine, does not reasonably provide enablement for generic agent combined with a particulate carrier or various particles claimed in claim 2 and as set forth below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Instant specification does not provide adequate support for the broadly claimed 'antiseptic', anti-inflammatory agents and wound healing promoting agents and 'particulate carrier'; for example, claim 27 defines an anti-inflammatory agent as antiseptic, antibiotic, corticosteroid and

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wound healing promoting agent; the specification also does not adequately describe what 'functional and cosmetic tissue remodeling' is and how the method is practiced as claimed in the method claims. Instant specification also does not teach how one can apply topically to the respiratory tract and treat or prevent diseases such as HIV and opportunistic diseases. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to liposomally encapsulated povidone iodine and treatment of specific diseases.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicant intends to convey by 'healing of wounds to the upper respiratory tract as claimed in claim 1. Are they internal wounds in the lung tissue?

Clarification of this is essential since method claims recite external application. The distinction between the anti-inflammatory agent, antiseptic and wound healing promoting agent in claim 1 is unclear. By reducing the inflammation and killing the microorganisms, the anti-inflammatory agents and anti-septic agents promote the healing and therefore are wound healing promoting agents. The examiner suggests naming of specific compounds.

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The distinction between liposomes and microspheres and nanoparticles in claim 2 is unclear. Depending upon the sizes, liposomes are either microspheres or nanoparticles (also in claims 3 and 26). The term, 'large' is a relative term and thus, indefinite. What is a 'laser pulse polymer coated molecule preparation?

'greatest' in claim 3 is a relative term. 'especially' is indefinite since it is unclear whether the expression following this term is indeed the limitation.

Proper Markush format with the expression 'selected from the group consisting of' and the use of the terms either 'and' OR 'or' only before the last Markush member should be followed in claims 4-6 7-8 and 28. The use of the terms such as 'including' 'as well as' in a Markush format is improper. Furthermore, claims 4 and 27 should recite specific Markush group members. Antibiotics and corticosteroids are specific class of compounds whereas 'antiseptic agents and wound-healing agents are very generic which includes the first two members.

Regarding claims 5, 6, 8, 14, 28-30 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The use of the term, 'including' in a Markush format is improper.

What are 'conserving agents' and 'consistency-forming agents' as recited in claim 14?

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Claim 15 is confusing. Isn't the active agent loaded in the preparation of claim 1? Furthermore, according to claim 1, the carrier is a particulate carrier; then how can that be in a solution form? (Also in claim 20). This claim requires a thorough restructuring.

What is an 'amphiphilic cream' as recited in claim 16?

'In case' in claim 20 is indefinite since the rationale for using this expression is unclear.

What is being conveyed through claims 22 and 42? Which is the disease to be treated? Is it the HIV infection or the opportunistic infection? Furthermore, opportunistic disease causing organisms such as P. Carini are present in the alveolar sacks which is in the lungs and not in the upper respiratory tract as the parent claim requires. What is meant by diseases of a suppressed immune system? How are they different from HIV? It is unclear how angina recited in claims 23 and 42 is connected with the upper respiratory tract.

What is being conveyed by 'functional and cosmetic tissue remodeling and repair treatment' as recited in claims 24 and 25?

What is meant by applying to said tract or ear in claim 25? Is it applied directly? Wherein the ear the composition is applied?

What is being conveyed through claim 27? The claim recites antiinflammatory agents and then recites the same combination of active agents recited in the parent claim.

What are the compounds recited in claims 5 and 28? Usually the compounds are made of metals and non-metals. For example silver halide is a metal compound as well as a

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halogen releasing compound. The examiner suggests the naming of specific compounds for all the categories.

What is 3w as recited in claim 40?

The examiner suggests a thorough revision and restructuring of ALL the claims and submit a clear copy of the claims.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 09/701450. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to similar compositions with an intended use language which has no

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significance in the composition claims. With regard to the method claims:- instant claims recite 'a method of preventing or treating upper respiratory tract by external application' whereas the method claims in the copending application are drawn to 'a method of preventing or treating lower respiratory tract by external application'. Since the terms 'upper' and 'lower' are relative terms there is an overlap between the portions of the respiratory tract and therefore, methods are obvious variants. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-24, and 43-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,863,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic language encompasses the specific components recited in the claims of said patent.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 1-4, 9-12, 14-16, 19-28, 31-33, 35-36, 39, and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Knight (5,049,388).

Knight discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Tables I and II, examples and claims).

10. Claims 1-4, 9-12, 14-16, 19-28, 31-33, 35-36, 39, and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Radhakrishnan (5,049,389).

Radhakrishnan discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

11. Claims 1-4, 9-12, 14-16, 19-28, 31-33, 35-36, 39, and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Prince (5,290,540).

Prince discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-10 microns. The drug combination includes antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

12. Claims 1-24 and 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 7-145081 or EP 0939373 of record.

JP and EP both disclose the same composition (note the abstract and the English translation). The intended use has no patentable significance in the composition claims.

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Claim Rejections - 35 U.S.C. § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 25-42, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight or Radhakrishnan or Prince cited above.

Knight, Radhakrishnan and Prince do not teach the administration of the composition for the infections which occur during cosmetic surgery. However, it is deemed obvious to one of ordinary skill in the art that the wound healing compositions can be applied during any state wherein the wounds are susceptible to infectious agents, with the expectation of similar anti-septic effect.

15. Claims 25-42, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP or EP in combination with knight or Radhakrishnan or Prince cited above.

The teachings of JP, EP, Knight, Radhakrishnan and Prince have been discussed above. What is lacking in JP or EP is the teaching of the use of the composition for the treatment of diseases caused by the microbes in the respiratory tract. In the absence of showing unexpected results, it is deemed obvious for one of ordinary skill in the art to use an anti-septic agent and a wound healing promoting agent taught by JP or EP to any part of the body including the respiratory tract, which has a microbial infection and a wound

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with the expectation of reasonable success since the references of Knight, Radhakrishnan and Prince show the common knowledge in the art of using a combination even for the respiratory tract.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

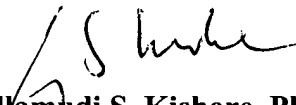
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 16, 2001